UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE WELLBUTRIN SR/ZYBAN ANTITRUST LITIGATION	Master File No. 02-CV-4398
THIS DOCUMENT RELATES TO:	Judge Bruce W. Kauffman
ALL ACTIONS	

DEFENDANTS' SUPPLEMENTAL REPLY IN SUPPORT OF MOTION TO DISMISS

Plaintiffs' Supplemental Memorandum makes two points worthy of response.

First, Plaintiffs say that the Third Circuit's decision in City of Pittsburgh v. West Penn Power Co., 147 F.3d 256 (3d Cir. 1998), is applicable "only in the unique context of 'regulated electric utility monopolies.'" (Pls.' Supplemental Memo. in Opp'n at 9.) Last week, Judge Glasser of the Eastern District of New York issued an opinion that puts the lie to that assertion. In re Tamoxifen Citrate Antitrust Litig., MDL No. 1408 (May 13, 2003) (attached as Exhibit 1).

Judge Glasser granted Fed. R. Civ. P. 12(b)(6) motions to dismiss antitrust class actions that one of Plaintiffs' co-lead counsel in this case, among others, had filed. The class actions sought to challenge an agreement between a brand drug company and a generic company settling a patent infringement litigation. Plaintiffs claimed that the settlement agreement had the effect of keeping other generics off the market. The court found, however, that plaintiffs had not adequately pled antitrust injury "because no

manufacturer ever received approval to market generic tamoxifen."[1] Id. at 23. Judge Glasser noted as follows:

> Antitrust injury, however, must be caused by something other than the regulatory action limiting entry to the market. For example, no antitrust injury was found where a potential competitor to a local electrical utility in Pittsburgh merged with the existing utility before receiving permission to compete from the state regulatory agency. City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 267-68 (3d Cir. 1998). Similarly, another court has found that no antitrust injury existed to support an antitrust counterclaim brought by a second ANDA filer since it would not be able to compete in the market until (1) the patent was declared invalid and (2) the 180-day exclusivity period expired for the first filer. See Bristol-Meyers Squibb v. Copley Pharm., Inc., 144 F. Supp. 2d 21, 23 (D. Mass. 2000).

Id. at 24-25. As Plaintiffs' counsel well know, Judge Glasser thus saw nothing in City of Pittsburgh that suggests that its reasoning and holding are applicable only in cases involving "regulated electric utility monopolies."[2] Both City of Pittsburgh and Tamoxifen support dismissal of this case.

Second, Plaintiffs complain that Defendants are presenting a "Catch-22 defense" under which no antitrust plaintiff could ever state a claim based on the filing of objectively baseless lawsuits. Although misstating the law applicable to this case, Plaintiffs are correct that it is difficult for an antitrust plaintiff who wishes to challenge another party's litigations to file a complaint that both satisfies the "objectively baseless"

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[1] Plaintiffs have admitted that no generic manufacturer has received FDA approval to market generic Wellbutrin® SR or Zyban®. (See Defs.' Reply Mem. in Support of Mot. to Dismiss at 9.) Plaintiffs have not disputed that this is a judicial admission that can be taken into account in ruling on a motion to dismiss.

[2] The portion of City of Pittsburgh that Plaintiffs cite (Pls.' Supplemental Memo in Opp'n at 9 n.4.) indicates only that the reasoning may not be applicable in the future if the electric utility industry were to be deregulated. Plaintiffs do not suggest that the

[Footnote is continued on next page]

standard of Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S. 49 (1993) ("PRE"), and adequately alleges causation. (See Defs.' Supplemental Mem. at 5-7.) This is no accident, nor is it a "Catch 22" situation. The filing of lawsuits is subject to broad immunity from challenge under the antitrust laws, and litigation that threatens to chill protected petitioning conduct is not supposed to be easy. As noted in GSK's Supplemental Memorandum, there are circumstances where an adequate antitrust complaint may be fashioned consistent with the First Amendment requirements articulated in PRE: where a generic applicant has obtained prompt tentative FDA approval but has to wait to sell the product until the thirty-month stay has expired. (Defs.' Supplemental Mem. at 7.) But those are not the circumstances presented here. Plaintiffs are correct in recognizing that they cannot allege a viable claim — not because GSK has misread the law, but because the factual basis for a valid claim does not exist.

[Footnote continued from previous page]

pharmaceutical industry has suddenly been deregulated such that generic companies no longer need FDA approval before selling their drugs.

Respectfully submitted,

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Dated: May 23, 2003

CERTIFICATE OF SERVICE

I certify that the foregoing Defendants' Supplemental Reply in Support of Motion to Dismiss was served on the counsel listed in the service list below on May 23, 2003.

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EXHIBIT 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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IN RE TAMOXIFEN CITRATE ANTITRUST LITIGATION

MEMORANDUM AND ORDER
MDL No. 1408 (ILG)

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GLASSER, District Judge:

SUMMARY

Plaintiffs are eighteen individuals (the "consumer plaintiffs"), eleven organizations (or their trustees) which provide certain medical benefits for their members (the "third-party payor plaintiffs"), and six consumer advocacy groups representing consumer plaintiffs (the "consumer advocacy plaintiffs") (collectively, "Plaintiffs"). Plaintiffs bring this action essentially alleging that defendant Zeneca, Inc. (together with co-defendant Astrazeneca Pharmaceuticals LP, "Zeneca") entered into an agreement with defendant Barr Laboratories, Inc. ("Barr") (collectively, "Defendants") that, while nominally settling an appeal of a judgment that declared the patent for the drug tamoxifen citrate ("tamoxifen") invalid, in fact monopolized and allocated the United States market for tamoxifen. Plaintiffs allege that this agreement violated the laws of the United States and the laws of twenty-two states. Defendants now move to dismiss the complaint on a variety of grounds. For the reasons states below, their motions are granted.

BACKGROUND

The actions involve the drug tamoxifen, the most essential drug for treatment of breast cancer.[1] Breast cancer is the most common malignancy and is one of the leading causes of death among women. During the 1990's, more than 1.5 million women in the United States were

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[1] Unless otherwise noted, the facts in this background are drawn from the Corrected Consolidated Class Action Complaint (the "Complaint") filed by Plaintiffs.

newly diagnosed with breast cancer. Tamoxifen is a synthetic hormone developed in the 1970's that is used, in addition to or in lieu of more drastic forms of therapy, to treat both early and advanced-stage breast cancer and to prevent recurrence. Tamoxifen has become the most widely prescribed treatment for breast cancer, and indeed is the single most-prescribed drug in the world for any cancer. The World Health Organization lists tamoxifen as an "Essential Drug," and tamoxifen is the standard of comparison in most clinical trials.

On August 20, 1985, Imperial Chemical Industries, PLC ("ICI") obtained United States Patent 4,536,516 (the '516 Patent) for tamoxifen. In December 1985 Barr filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"), requesting approval to sell a generic bioequivalent version of the pioneer drug tamoxifen. An ANDA filing is governed by the Hatch-Waxman Act, 21 U.S.C. § 355, which provides an expedient method of obtaining FDA approval to bring generic bioequivalent drugs to the market. In addition to affirming that the generic drug contains the same active ingredient(s) as the patented drug already approved and listed by the FDA, an ANDA filer must certify why the patent would not be infringed pursuant to one of four reason:

I. No patent was in fact filed for the pioneer drug;

II. The patent for the pioneer drug has expired;

III. The patent for the pioneer drug will expire on a particular date *and* the ANDA filer will not market its generic product before that date; or

IV. The patent for the pioneer drug is invalid or will not be infringed upon the proposed generic product.

See 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

Upon the filing of an ANDA with a paragraph IV certification, the holder of the patent whose validity is being questioned may bring an action for declaratory judgment against the

ANDA filer. Such a lawsuit has the effect of staying FDA consideration and approval of the ANDA for thirty months or until the date of a court decision as to the validity of the patent, whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iii). A court, in its discretion, however, may extend the stay if the litigation is not resolved within the thirty month period. *See id.* One of the benefits of being the first ANDA filer to obtain FDA approval is an exclusive 180-day period in which to sell the generic drug free from other generic drug competition. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day period of market exclusivity is triggered either by the first sale of the applicant's product or when a court determines either that the patent is invalid or will not be infringed, whichever is earlier.[2] *Id.*

Barr's ANDA application, as amended in September 1987, certified that the '516 Patent was invalid and unenforceable. Within forty-five days of receiving notice of Barr's ANDA application, ICI sued Barr for patent infringement in the Southern District of New York.[3] ICI's patent infringement suit against Barr was tried before the late Honorable Vincent L. Broderick. On April 20, 1992, Judge Broderick held that the '516 Patent was invalid and unenforceable because ICI wrongfully withheld relevant material from the United States Patent and Trademark Office. *Imperial Chem. Industries, PLC v. Barr Labs., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992) ("*ICI v. Barr*"). ICI appealed that determination to the Federal Circuit.

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[2] At the time of Barr's ANDA, the court determination trigger was interpreted to be a final, non-appealable decision by a court. In light of two subsequent district court decisions, the FDA amended its regulation defining "court action" so that a district court determination of patent invalidity is now considered to be a final decision triggering the 180-day exclusivity period. *See* 21 C.F.R. § 314.107(e) (interim rule).

[3] ICI's lawsuit also named as a defendant Heumann Pharma GmbH & Company ("Heumann"), Barr's supplier of tamoxifen. Heumann was subsequently dismissed from the suit in accordance with the terms of a stipulation of settlement. According to the Complaint, Heumann agreed to be bound by any determination of the validity of the '516 Patent.

Zeneca and Barr Settle the Patent Infringement Dispute

In 1993, while the appeal was pending, Zeneca (which had recently succeeded to ICI's rights in the '516 Patent) and Barr entered into a settlement agreement (the "Settlement Agreement"). Pursuant to the Settlement Agreement, Barr withdrew its challenge to the validity of the '516 Patent and amended its ANDA application to certify that it would not seek to market its generic version of tamoxifen until the patent expired. In return, Zeneca paid Barr $21 million and licensed Barr to sell tamoxifen manufactured by Zeneca in the United States, including Puerto Rico and the District of Columbia. The Settlement Agreement was conditioned upon the Federal Circuit vacating Judge Broderick's judgement declaring the '516 Patent invalid.[4]

Plaintiffs allege that, as part of the Settlement Agreement, Barr and Zeneca also agreed that Barr would not commercially market its generic product to avoid triggering the 180-day exclusivity period. Zeneca and Barr's understanding allegedly was that, although Barr's ANDA application would be amended to paragraph III, if a subsequent ANDA filer successfully invalidated the '516 Patent then Barr would insist upon its exclusivity rights (as the first paragraph IV filer) and not commercially market the generic until 2002, thereby delaying the triggering of the 180-day exclusivity period.

Barr and Zeneca filed a Joint Motion to Dismiss the Appeal as Moot and to Vacate the Judgment Below. No copy of the Settlement Agreement was presented to the Court of Appeals. Sidmak Laboratories, Inc. ("Sidmak"), a generic drug manufacturer, sought leave to file, untimely, a brief as amicus curiae objecting to dismissal of the appeal. On March 19, 1993, the

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[4] Zeneca also promised to pay Heumann a sum of cash equal to $9.5 million at the time of settlement and $35.9 million over a ten year period in exchange for Heumann's promise to discharge all claims related to the '516 Patent.

Federal Circuit granted the joint motion pursuant to its practice at the time to honor settlement agreements and denied Sidmak's motion. *See Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811 (table) (Fed. Cir. Mar. 19, 1993).[5] On March 23, 1993 Judge Broderick vacated the judgement and dismissed the case. Consequently, the '516 Patent remained valid, and Zeneca's Nolvadex® brand and Barr's licensed version of tamoxifen were the only products on the market. Although Barr could produce tamoxifen at a lower cost than the price at which it obtains tamoxifen from Zeneca under license, Barr's ability to price the licensed version is restrained by that higher cost.

Subsequent ANDAs for Tamoxifen

In June 1994, Novopharm Ltd. ("Novopharm") filed an ANDA for tamoxifen that claimed the '516 Patent was invalid.[6] Subsequently, on January 18, 1995 Zeneca sued Novopharm for patent infringement. Before discovery began, Novopharm moved for summary judgment on the basis that the *ICI v. Barr* Judgment should be given preclusive effect and that the *vacatur* should be ignored. (Change Dec., Ex. 8.) The district court disagreed. *Zeneca Ltd. v. Novopharm Ltd.*, 923 F. Supp. 75 (D. Md. 1995). After discovery was completed, Novopharm again moved for summary judgment, this time arguing that the court should adopt two factual

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[5] Since that time, the Supreme Court has ruled that federal appellate courts may not direct the *vacatur* of a district court order based solely on a settlement agreement between the parties. *See United States Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18, 27 (1994). However, the Federal Circuit subsequently held that *United States Bancorp* applied only to cases still pending when *United States Bancorp* was decided, and thus the *vacatur* (issued prior to *United States Bancorp*) was proper. *See Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (Table), 1997 WL 168318, at *2 (Fed. Cir. Apr. 10, 1997).

[6] The facts about the Novopharm ANDA and subsequent litigation are not in the Complaint, but are based on court decisions publicly available on Westlaw and papers submitted to those courts. (*See* Chang Dec., Exs. 8-11).

findings made in the vacated judgment in *ICI v. Barr* under the doctrine of issue preclusion. *Zeneca Ltd. v. Novopharm Ltd.*, 919 F. Supp. 193, 196 (D. Md. 1996). Again the district court denied the motion, *id.* at 196-98, and subsequently found that Zeneca did not engage in inequitable conduct before the PTO, and therefore granted judgment to Zeneca upholding the validity of the '516 Patent. (Chang Dec., Exs. 9 and 10.) On appeal, the Federal Circuit affirmed the validity of the '516 Patent in an unpublished decision. *Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144, 1997 WL 168318 (Fed. Cir. Apr. 10, 1997) (Table).

In August 1994, Pharmachemie, B.V. ("Pharmachemie") submitted an ANDA with a paragraph III certification for its version of tamoxifen. In February 1996, Pharmachemie amended its ANDA to include a paragraph IV certification. Zeneca then sued Pharmachemie for patent infringement within 45 days of the amendment, *see Zeneca Ltd. v. Pharmachemie, B.V.*, Civ. No. 96-21413 (RCL) (D. Mass.), triggering the statutory 30-month stay. The FDA gave tentative approval to Pharmachemie's ANDA on April 3, 1997. Before the 30-month stay expired, Zeneca moved the court to extend the stay. The motion was denied in a published decision. *Zeneca Ltd. v. Pharmachemie, B.V.*, 16 F. Supp. 2d 112 (D. Mass 1998). Although not mentioned in the Complaint, prior to trial the district court granted Zeneca's motion for partial summary judgment on the issues of collateral estoppel, patent misuse, and unclean hands. *Zeneca Ltd. v. Pharmachemie, B.V.*, 37 F. Supp. 2d 85 (D. Mass. 1999). At trial, Pharmachemie argued that the '516 Patent was unenforceable because Zeneca had engaged in inequitable conduct before the PTO and that the patent was invalid because it did not set forth the "best mode" for carrying out the invention, as required by 35 U.S.C. § 112. *Zeneca Ltd. v. Pharmachemie, B.V.*, Civ. No. 96-21413 (RCL), slip op. at 3 (D. Mass. Sept. 14, 2000). The

court granted judgment as a matter of law to Zeneca on the inequitable conduct claim, and a jury returned a verdict in Zeneca's favor on the best mode claim. *Id.* at 4-5. No appeal was taken.

In January 1996, Mylan Pharmaceuticals, Inc. ("Mylan") submitted an ANDA with a paragraph IV certification for its version of tamoxifen. Zeneca sued Mylan in the Western District of Pennsylvania for patent infringement within 45 days of that certification, also thus triggering the 30-month statutory stay of FDA approval for Mylan's ANDA. Mylan then agreed to follow the *Pharmachemie* court's decision, and the case was dismissed after that court ruled in favor of Zeneca. *Zeneca Ltd. v. Mylan Labs.*, No. 96-333 (W.D. Pa. Nov. 30, 2000).

Barr's Petition to the FDA

While Mylan and Pharmachemie's actions were pending before the district courts, on June 26, 1998, Barr filed a Petition for Stay of Action with the FDA to block final marketing approval for Mylan's ANDA (the "FDA Petition"). Although Barr had amended its ANDA from a paragraph IV certification to a paragraph III certification after the *ICI v. Barr* settlement, Barr contended in its FDA Petition that it was entitled nonetheless to the 180-day exclusivity period as the first paragraph IV filer. The FDA acceded to Barr's petition and announced in a letter to Barr, dated March 2, 1999, that it would stay any approval of tamoxifen ANDAs until 180 days after the date of the first commercial marketing of the drug under Barr's ANDA or the date of a final court decision holding the tamoxifen patent to be invalid or not infringed.

Pharmachemie and Mylan later successfully challenged this decision in court. *Mylan Pharmaceuticals, Inc. v. Henney*, 94 F. Supp. 2d 36, 54 (D.D.C. 2000), *vacated as moot sub nom. Pharmachemie, B.V. v. Barr Labs., Inc.*, 276 F.3d 627 (D.C. Cir. 2002). In response to the district court's order, on June 26, 2000 the FDA revoked Barr's eligibility for the 180-day exclusivity period.

Allegations Regarding Injury

Plaintiffs essentially allege that but for the Settlement Agreement, the judgment declaring the '516 Patent invalid would have been affirmed, Barr's 180-day exclusivity period would have been triggered, and a competitive market for tamoxifen would have resulted. Plaintiffs further allege that Zeneca and Barr maintain a duopoly in which Zeneca illegally shares its monopolistic profits with Barr through the licensing agreement. The discount for purchasing tamoxifen distributed by Barr is only about 5% compared to the price for Zeneca's brand name version, Nolvadex®. Plaintiffs allege that because the Settlement Agreement permits Zeneca and Barr to charge artificially inflated prices, Plaintiffs were overcharged for tamoxifen.

Procedural History

The Settlement Agreement has spawned thirty lawsuits around the country, all of which have been transferred to this Court, pursuant to 28 U.S.C. § 1407, by the Judicial Panel on Multi-District Litigation for coordination of pre-trial matters. A coordinated class action complaint was subsequently filed. The complaint alleges that the Settlement Agreement enabled Zeneca and Barr to (I) resuscitate a patent that Barr had established by clear and convincing evidence was invalid and unenforceable; (ii) confine the entire United States market for tamoxifen to one manufacturer, Zeneca; (iii) share the monopoly profits of Zeneca's tamoxifen; (iv) avoid price competition and maintain artificially inflated market prices for Nolvadex® and its Zeneca-manufactured generic licensed to Barr; and (v) exclude competition from other generic manufacturers. (*See* Compl. ¶53.) The Complaint further alleges that but for the Settlement Agreement, Judge Broderick's judgment would have been affirmed, the FDA would have granted final approval to Barr's generic version of tamoxifen, Barr would have marketed a generic version of tamoxifen, a highly competitive market for tamoxifen would have developed after

Barr's 180-day exclusivity period had run, and Zeneca would have been collaterally estopped from enforcing the '516 Patent against other ANDA filers. (*See id.* ¶54.) Plaintiffs also allege that by refusing to market a generic version of tamoxifen, Barr could prevent another challenger to the '516 Patent from being able to market the generic counterpart.

STANDARD FOR MOTION TO DISMISS

When deciding a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the court must take all allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957); *Niagara Mohawk Power Corp. v. Federal Energy Reg. Comm'n*, 306 F.3d 1264, 1267 (2d Cir. 2002). A complaint should not be dismissed "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *FD Property Holding, Inc. v. US Traffic Corp.*, 206 F. Supp. 2d 362, 369 (E.D.N.Y. 2002) (internal quotation marks omitted). However, the Court may consider matters of public record, such as court decisions, statutes, and documents such as briefs filed with courts and other public bodies. *See, e.g., Papasan v. Allain*, 478 U.S. 265, 268 n.1 (1986) ("Although this case comes to us on a motion to dismiss under Federal Rule of Civil Procedure 12(b), we are not precluded in our review of the complaint from taking notice of items in the public record . . . ."); *Rothman v. Gregor*, 220 F.3d 81, 92 (2d Cir. 2000).

DISCUSSION

I. Whether the Settlement Agreement Violated the Sherman Act

A. General Principles

Section 1 of the Sherman Act provides: "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. . . ." 15 U.S.C. § 1.

As a general rule, an agreement between a monopolist and a potential competitor to divide the market between them and exclude other competition is per se illegal under Section 1. *See United States v. Topco Assoc., Inc.*, 405 U.S. 596, 608 (1972) ("One of the classic examples of a per se violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition.").

However, the holder of a patent legally maintains a monopoly over his or her product and may "prevent other[s] from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S 100, 135 (1969). A patent holder also "may assign to another his patent, in whole or in part, and may license others to practice his invention." *Id.* "Simply stated, a patent holder is permitted to maintain his patent monopoly through conduct permissible under the patent laws." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981).

This permissible conduct includes the settlement of patent litigation by a licensing agreement. *See Standard Oil Co. v. United States,* 283 U.S. 163, 170 (1930) ("Where there are legitimately competing claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act."); *Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1220 (4th Cir. 1976) ("the settlement of patent litigation, in and of itself, does not violate the antitrust laws"); *Scientific Corp. v. Schneider (Europe) AG*, 983 F. Supp. 245, 269 (D. Mass. 1997) ("It is well established that settlement of patent litigation through a cross-licensing agreement does not in and of itself violate the antitrust laws."), *appeal dism'd*, 152 F.3d 947 (Fed. Cir. 1998) (Table).

B. Bad Faith Patent Settlements Can Violate the Antitrust Laws

A patentee, however, cannot go "beyond the limits of the patent monopoly." *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948). As the Supreme Court held in *Standard*

Oil, the very case that established that patent settlements do not alone violate the antitrust laws: "*Any* agreement between competitors may be illegal if part of a large plan to control interstate markets." 283 U.S. at 169 (emphasis added).

For example, in *United States v. Singer Co.*, 374 U.S. 174 (1963), Singer and a Swiss company Gegauf (along with a third Italian company) settled threatened and actual interference proceedings before the United States Patent Office (the precursor to the modern PTO) by, *inter alia*, cross-licensing patents regarding sewing machines to one another. Thereafter, Gegauf assigned its patent application to Singer which then received the patent. Evidence showed that Singer and Gegauf also sought the power to better enforce these patents against Japanese competitors who might seek to import sewing machines into the United States that infringed upon Gegauf's patents. *Id.* at 191, 195 n.9. Singer undertook steps to exclude the Japanese competition by bringing a proceeding before the United States Tariff Commission (which only an American company like Singer could do) to exclude all foreign machines that fell within *Gegauf's* patent from entering the United States. *Id.* at 1987-88, 195-96. Although the District Court found that no illegal conspiracy existed because the primary purpose of the agreements was to settle the patent disputes, the Supreme Court reversed and found that Singer had gone beyond protecting its own patents and instead had combined with Gegauf against other competitors. *Id.* at 194. In his concurring opinion, Justice White was most troubled by the possibility that by not pursuing the interference claims, Singer and Gegauf collusively deprived the Patent Office of notice of prior art that would sap the proposed patent of the novelty that justifies a patent monopoly in the first place. *Id.* at 199-200 (White, J., concurring).

As explained by the Fourth Circuit,

> It is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize trade that antitrust violations occur. . . . *Singer* makes clear that it is not the mere act of settlement but the intent of the parties in entering into that settlement and their actions pursuant thereto that, in law constitute such a violation [of the Sherman Act].

Duplan Corp., 540 F.2d at 122-21.[7] In other words, Plaintiffs can establish a Sherman Act violation by alleging facts from which it can be inferred that Zeneca and Barr entered into the Settlement Agreement in bad faith and used the agreement to restrain or monopolize trade.

C. Application of Antitrust Laws to Patentee-ANDA Applicant Settlements

In opposition to the motion to dismiss, Plaintiffs point out that at least three courts have reviewed allegedly bad faith settlements between patentees and ANDA filers and found that Sherman Act claims can be stated for reasons similar to those set forth in *Singer*. Plaintiffs argue that this case is comparable to these other cases, and that their allegations accordingly state a claim under the Sherman Act. Because each case arises under its own complex set of facts, those facts are set forth here in some detail.

1. Terazosin Hydrochloride

Abbott Laboratories registered patents regarding the drug terazosin hydrochloride ("terazosin") and received approval to market it for the treatment of hypertension and enlarged prostate. *See In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1343 (S.D. Fla. 2000), *pet. appeal granted*, No. 02-101-71-J (11th Cir. Apr. 19, 2002). Subsequently two generic manufacturers, Zenith Goldline Pharmaceuticals, Inc. and Geneva Laboratories, filed

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[7] In *Duplan Corp.*, the court held that the illegality of such an agreement could not be presumed solely by the existence of a letter from a settling party's attorney opining that the party would prevail if it pursued the patent infringement case. 540 F.2d at 1221.

ANDAs with paragraph IV certifications challenging the validity of Abbott's patents and began racing toward first approval from the FDA. *Id.* at 1343-44. By late March 1998, although Abbott was engaged in infringement litigation with both challengers, the 30-months stays were expiring and both Zenith and Geneva were poised to begin marketing generic versions of terazosin. *Id.* at 1345-46.[8]

However, Abbott settled its litigation with Zenith by paying $3 million up front, and $6 million per quarter on condition that Zenith did "not sell, offer for sale, donate or otherwise commercially distribute in the United States" terazosin, and upon Zenith's promise not to assist any other company to gain FDA approval to market terazosin. *Id.* at 1346. With regard to Geneva, Abbott agreed to pay $4.5 million per month to Geneva to refrain from marketing any generic terazosin until any other generic began selling or until Geneva received a final, unappealable judgment that its generic terazosin did not infringe Abbott's patents. *Id.* However, Geneva and Abbott would continue to litigate the issue, but Geneva would support Abbott in extending the 30-month stay and promised "to use its best efforts to oppose any attempt by any ANDA applicant" to market generic terazosin prior to the date provided for in then-existing FDA regulations. *Id.* at 1347 & n.7. In other words, *Terazosin* involved two simultaneous horizontal agreements – one permanently ending possible competition from Zenith, and another buying time and cooperation from Geneva.

In an antitrust action, the district court found that by these agreements "Geneva and Zenith foreswore competing with Abbott in the United States market for terazosin hydrochloride

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[8] With regard to Zenith, on October 1, 1997, Zenith's motion for preliminary injunctive relief was denied. *Terazosin*, 164 F. Supp. 2d at 1345. Zenith's appeal of that order was pending before the Federal Circuit when the parties settled. *Id.* at 1346. With regard to Geneva, patent infringement litigation was proceeding apace in the Northern District of Illinois.

drugs and promised to take steps to forestall others from entering the markets in exchange for millions of dollars . . . ." *Id.* at 1348-49. The court held that such agreements were blatantly anti-competitive by dividing the market among competitors (a horizontal restraint) and that such agreements were illegal *per se*. *Id.*

2. Cardizem CD

Marion Merrell Dow ("Dow") introduced in 1982 a new pioneer drug (diltiazem hydrochloride) for treating hypertension and angina that was patented and marketed in a once-daily, immediate-release delivery method under the name Cardizem. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 629 (E.D. Mich. 2000) ("*Caridzem I*"). Eventually, the product was improved by releasing it in a once-daily "sustained release" delivery method produced under license from a separate patent holder ("Elan"), and rebranded as Cardizem CD. *Id.* In 1992, Biovail International Corporation began developing its own once-daily generic of Cardizem, and began working with Hoechst-Roussel Pharmaceuticals ("HRP") to develop a sustained release delivery method of its own to be called Tiazac. *Id.* Upon HRP's filing an ANDA stating that Tiazac did not infringe on Cardizem's patents, Dow sued for patent infringement on November 11, 1993.

In late 1994, HRP's parent Hoechst AG agreed to acquire Dow, and HRP ended its partnership with Biovail. *Id.* at 630. Biovail in turn sued Hoechst for breach of contract and antitrust violations, and the parties reached a master settlement of both litigations in 1995 in which they agreed not to challenge each others' respective products. *Id.* After an FTC investigation into the Hoechst-Dow merger, Hoechst agreed to support Biovail's applications to the FDA for approval of Tiazac by directing the FDA to reference Biovail's applications with its own studies used for Cardizem. *Id.* The only remaining barrier to Tiazac's entry to the market

was an outstanding patent dispute between Biovail and Elan over the delivery method. *Id.* When Hoechst discovered that the Biovail-Elan litigation would be settled, however, and that Biovail intended to file a New Drug Application (rather than an ANDA) to avoid the 180-day exclusivity period to which another generic manufacturer (Andrx) already had claim, Hoechst refused to permit Biovail to reference the studies. *Id.* Accordingly, without clinical studies that Biovail could reference, the FDA refused to license Tiazac. *Id.* at 631.

Meanwhile, in September 1995 Andrx had filed its ANDA certifying that Cardizem would not be infringed, and Hoechst sued for patent infringement in January 1996 thereby triggering the 30-month stay. *Id.* On September 17, 1997, the FDA preliminarily approved Andrx's generic version of Cardizem CD, which meant that Andrx could have begun marketing the product as early as July 4, 1998. *Id.* at 632. Shortly thereafter, Hoechst and Andrx entered into an agreement, by the terms of which Andrx would refrain from marketing its generic version of Cardizem CD until all appeals in the litigation were concluded and would receive quarterly payments of $10 million from Hoechst beginning on July 9, 1998. *Id.*

By August 20, 1998, consumer plaintiffs began filing lawsuits alleging violations of indirect purchaser state laws. *Id.* On June 9, 1999, Hoechst settled its patent litigation with Andrx by paying Andrx an additional $50 million. *Id.* The district court held that the agreement was a naked restraint on trade subject to *per se* analysis, and granted plaintiffs partial summary judgment. *See In re Cardizem Antitrust Litig.*, 105 F. Supp. 2d 682, 699-705 (E.D. Mich. 2000) ("*Cardizem II*"), *appeal filed*, No. 00-2483 (6th Cir. Dec. 19, 2000).

3. Procardia XL

Pfizer, Inc. ("Pfizer") filed a New Drug Application for extended release nifedipine, a hypertension treatment, which Pfizer markets in three strengths (30, 60 and 90 mg) under the

brand name Procardia XL. *See Biovail, Inc. v. Mylan Labs, Inc., et al.*, Civ. No. 1:01CV66, slip op. at 5 (N.D. W. Va. Mar. 22, 2002). In April 1997, Mylan filed an ANDA for 30 mg nifedipine with the FDA. *Id.* Pfizer sued Mylan for patent infringement, and the case settled in March 2000, under terms by which Mylan received a license for a "private label" version of Procardia, and Mylan would not market its generic version covered by its ANDA. *Id.*, slip op. at 5-6.

Biovail filed its ANDA for 30 mg and 60 mg nifedipine after Mylan's filing, but was unable to market either version until one of its licensees forced the FDA's hand by petitioning for final approval, which the FDA granted on February 6, 2001. *Id.*, slip op. at 6. The FDA ruled that Mylan had effectively converted its paragraph IV certification to a paragraph III certification upon settling with Pfizer, and that marketing the "private label" version triggered the 180-day exclusivity period. *Id.*, slip op. at 6-7.

Biovail then sued Mylan and Pfizer for unreasonably restraining trade by agreeing to reduce competition and hindering Biovail's entry into the market for four months. Biovail claimed that because buyers in the market for Procardia XL prefer to obtain different dosage strengths from the same supplier, the restrictions on 30 mg Procardia XL prevented Biovail from marketing effectively its 60mg version. *Id.* The district court found that these allegations were sufficient to state a claim that Mylan and Pfizer conspired to produce anti-competitive effects. *Id.*, slip op. at 11.

D. Analysis

Defendants claim that the Settlement Agreement at issue here is unlike the agreements found suspect in other cases, and that it is a defensible resolution of patent litigation and not a restraint of trade. Further, Defendants argue that further inquiry into the vacated decision "would

effectively strip settlements of value and finality by permitting collateral suits by third parties who were allegedly deprived of a 'favorable' decision." (Def. Consolidated Reply Mem. at 7.)

1. Plaintiff's Claims Are Not an Impermissible Collateral Attack on the *Vacatur* Order

Defendants argue that *vacatur* was an appropriate course for the Federal Circuit to take given precedent current at the time. (Def. Consolidated Mem. at 27-30), a point which Plaintiffs do not contest. (Pl. Opp. Mem. at 45.) Defendants further argue that Plaintiffs' claims are fundamentally inconsistent with the *vacatur*, comparing this to a collateral attack on a judgment. However, there is a difference. As noted by Defendants, with *vacatur* potential future litigants (such as Plaintiffs) are no worse off because "the only damage to the public interest is that the validity of [the intellectual property rights] *would be left to future litigation*." *Major League Baseball Properties, Inc. v. Pacific Trading Cards, Inc.*, 150 F.3d 148, 152 (2d Cir. 1998) (settlement of trademark dispute) (emphasis added).

Plaintiffs are not trying to deprive the settlement of its value to either party, since both parties have apparently received the benefit of the bargain – Zeneca was able to eliminate a significant challenge to the validity of its '516 Patent, and Barr was well compensated. If Plaintiffs can allege facts that the Settlement Agreement was executed in bad faith, they will have stated a claim that the Settlement Agreement was an illegal restraint of trade. Accordingly, this Court will examine whether the allegations in the Complaint state claims as a matter of law.

2. The Zeneca-Barr Settlement Agreement is Different from Other Patentee-ANDA Agreements

Defendants claim that even if settlements between patentees and ANDA filers are not immunized from antitrust scrutiny, the Settlement Agreement between Zeneca and Barr is

significantly different from those found in other cases to violate the Sherman Act. Defendants are correct.

a. The Settlement Agreement Terminated the Entire Litigation

One crucial difference is that the Settlement Agreement in fact ended the litigation outright. Barr and Zeneca actually resolved their complex litigation, and in so doing they cleared the field for other generic manufacturers to challenge the patent. Indeed, at least three other generic manufacturers accepted the challenge, filed ANDAs with paragraph IV certifications, and in each case, Zeneca successfully litigated the validity of the '516 patent.

In comparison, in *Cardizem*, Hoechst paid Andrx to refrain from marketing its generic after the 30 months stay expired, but did not otherwise end the litigation. 105 F. Supp. 2d at 632. Similarly, in *Terazosin*, the patentee settled outright one case (the Zenith Agreement), but took advantage of the existence of a second case to prolong the 30 month stay. 164 F. Supp. 2d at 1346-47. Of course, these sorts of agreements sap a generic filer's motivation to finish the litigation, and therefore produce a perverse result under the Hatch-Waxman Act by providing an incentive to delay the patent litigation without "clearing the way" for other ANDA filers. In the end, these agreements meant that the litigation could drag on without providing other generic manufacturers (even those who were not sued for patent infringement like Biovail) a means by which to enter the market.

The same cannot be said about the present agreement. The conclusion of the litigation meant that other ANDA filers were free to litigate the validity of the '516 patent. Instead of leaving in place an additional barrier to subsequent ANDA filers, the Settlement Agreement in fact removed one possible barrier to final FDA approval – namely, the existence of ongoing litigation between an existing ANDA filer and a subsequent filer.

b. Barr's FDA Petition Five Years After the Settlement Agreement Cannot Serve as a Basis for Liability

Plaintiffs contend that Defendants' argument regarding "clearing the field" for other ANDA filers is belied by Barr's FDA Petition (allegedly pursuant to the Settlement Agreement) that sought to preserve Barr's 180-day exclusivity period. Barr's FDA Petition was premised on an interpretation of FDA regulations that only Barr's own marketing of a generic version of tamoxifen or a final court decision could trigger the 180-day period. Given the existence of two pending infringement suits, Barr's FDA Petition sought to assert that its previous ANDA was superior in determining who might receive the 180-day exclusivity period.[9]

Two of the bases for the FDA Petition came only years after the Settlement Agreement. First, until 1997, FDA regulations interpreting the 180-day exclusivity period made it clear that the ANDA filer which first successfully defended against the patent infringement suit would receive the 180-day exclusivity period. The relevant language of the Hatch-Waxman Act provides, however, that a subsequent ANDA paragraph IV application "shall be made effective not earlier than one hundred and eighty days after – (I) the date [the] Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier." 21 U.S.C. 355(j)(5)(B)(iv).

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[9] It must be noted that Barr did *not* seek similar relief when Novopharm filed its ANDA and challenged the '516 patent between 1994 and 1997. Only after the events in 1997 and 1998 described above in the text did Barr attempt to assert its rights. If Barr intended to protect its exclusivity period on behalf of itself and Zeneca *pursuant to the Settlement Agreement*, Barr's inactivity during the pendency of the Novopharm litigation is inexplicable.

In light of the actual language of the Hatch-Waxman Act, in 1997 a district court invalidated the FDA's "successful defense" regulation on the grounds that it contradicted the unambiguous language of the Hatch-Waxman Act. *See Mova Pharmaceuticals Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997) (enjoining FDA from giving final approval to second ANDA filer who successfully defended against patent infringement suit). The Court of Appeals for the District of Columbia Circuit upheld this decision on the grounds that the successful defense regulation was inconsistent with the statutory language and that the plain meaning of the statutory language would not produce an absurd result. *See Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060, 1070-73 (D.C. Cir. 1998).

In other words, until 1997, if Novopharm, Pharmachemie or Mylan had successfully defended against Zeneca's patent infringement suit, the first one to do so would receive the 180-day exclusivity period pursuant to then-existing FDA regulations. After the *Mova Pharmaceuticals* decisions in 1997 and 1998, Barr's claim to the 180-day exclusivity period was strengthened significantly (if not wholly created) since the FDA could not permit the applications of the other generic manufacturers to take effect until 180 days elapsed after such a court decision.

Second, the FDA specifically argued in the *Mova Pharmaceuticals* appeal that its regulations requiring that an ANDA filer who loses the patent infringement suit be treated as a paragraph III filer was "housekeeping" and not intended to affect the application of the 180-day exclusivity period. *Id.*, 140 F.3d at 1070. Although the D.C. Circuit confessed some disbelief at this interpretation, it was willing to defer to the FDA's interpretation regarding an issue not directly before the court. *Id.* at 1070 n.13 ("We confess to not understanding how the FDA can

reconcile its reading with the language of its own regulation, but stress that this issue has not been briefed and is not necessary to the decision in this case.")[10]

Two months after the D.C. Circuit's decision in *Mova Pharmaceuticals*, Barr filed its FDA Petition. Barr argued that the Hatch-Waxman Act, as interpreted by the D.C. Circuit, required that the FDA stay approval of Mylan's ANDA application since the FDA regulation requiring a "successful defense" were no longer valid. Barr also used the FDA's own arguments before the D.C. Circuit to support its position that, notwithstanding the paragraph III amendment Barr filed after the Settlement Agreement, it should be entitled to the 180-day exclusivity period whenever and by whomever the period was triggered.

Barr's FDA Petition was thus an attempt to petition a governmental body in order to protect an arguable interest in a statutory right based on recent developments in the court and at the FDA. As such, the FDA Petition was protected activity under the First Amendment, and long-settled law established that the Sherman Act, with limited exceptions, does not apply to petitioning administrative agencies.[11] *See Eastern R.R. Presidents Conference v. Noerr Motor*

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[10] The district court that reviewed the FDA's decision to grant Barr's FDA Petition criticized and rejected this confusing interpretation of the interplay between paragraph III and paragraph IV certification. *See Mylan Pharm. v. Henney*, 94 F. Supp. 2d 36, 57 (D.D.C. 2000), *vacated as moot sub nom., Pharamachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627 (D.C. Cir. 2002).

[11] Plaintiffs admit they cannot and do not seek to argue that Barr's FDA Petition falls within the sham exception to the *Noerr-Pennington* doctrine. (Pl. Opp. Mem. at 52-53.)

Given the disposition of these motions, this Court need not address the more difficult question of whether the Settlement Agreement itself is protected by the *Noerr-Pennington* doctrine. *Compare Hise v. Philip Morris, Inc.*, 46 F. Supp.2d 1201, 1206 (N.D. Okla. 1999), *aff'd*, 208 F.3d 226 (10th Cir. 2000) (holding that concerted activities *among co-defendants* in jointly negotiating Master Settlement Agreement with 46 states and 6 other jurisdictions was protected activity) *with Cardizem*, 105 F. Supp. 2d at 641 (collecting and agreeing with cases that hold settlements *between adverse parties* are not protected); *see* Raymond Ku, *Antitrust Immunity, the First Amendment, and Settlements: Defining the*

Freight, Inc., 365 U.S. 127 (1961) (Sherman Act does not apply to joint lobbying of state legislature); *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965) (extending *Noerr* to joint activity to persuade administrative agency). Of course, as described below, plaintiffs are also unable to allege any anti-competitive impact from Barr's FDA Petition, both because the FDA's decision in Barr's favor was overturned, *see Mylan Pharm. v. Henney*, 94 F. Supp. 2d 36, 57 (D.D.C. 2000), *vacated as moot sub nom.*, *Pharmachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627 (D.C. Cir. 2002), and because no generic manufacturer in fact ever received approval to enter the market.

c. The Allegations Lack the Continuing Behavior Found in Other Cases

The present case is also different in that no pattern of settlements or continuing behavior is involved. For example, in *Singer*, doubts arose over Singer's petition to the Tariff Commission because of references to another company (Pfaff) in Gegauf's assignment of rights. Singer and Gegauf returned to the negotiating table to delete those references, a "maneuver . . . for the purpose, as the trial court found, of giving Singer a better chance of prevailing before the Tariff Commission in its efforts to exclude infringing machines." *Singer*, 374 U.S. at 196. The Court found that the conspiracy was "clearly illustrated" by this type of continuing behavior of Singer and Gegauf. *Id.* at 195.

No similar maneuvering or continued behavior is alleged here. Certainly, there are no allegations that Zeneca and Barr ever acted in concert after the 1993 Settlement Agreement, and only one allegation (the Barr FDA Petition) of any allegedly anti-competitive activity after the

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Boundaries of the Right to Petition, 33 Ind. L. Rev. 385, 429 (2000) (arguing that *Noerr-Pennington* would not apply because "when asked to approve a settlement agreement, a court is not being asked to determine liability or approve the substance of the agreement.").

Settlement Agreement was executed. Indeed, the only pattern of behavior discerned from the Complaint appears to be a vigorous defense of the '516 patent. Zeneca challenged every ANDA filer, and defeated the claims of patent invalidity on the merits on two occasions (not including Mylan's decision to tie its fate to Pharmachemie's). While there may conceptually be a case where bad faith can be alleged based on a single event, the allegations here do not state a claim for bad faith settlement.

II. Plaintiffs Have Not Suffered Antitrust Injury

Plaintiffs' Sherman Act claims also fail to adequately plead antitrust injury. In order to state a claim under the Sherman Act, a plaintiff must allege facts that in addition to causation show "antitrust injury, which is to say [1] injury of the type the antitrust laws were intended to prevent and [2] that flows from that which makes defendants' acts unlawful. The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Brunswick Corp. v. Pueblo Bowl-o-Mat, Inc.*, 429 U.S. 477, 489 (1977).

A. Plaintiffs Suffered No Injury From the Settlement Agreement Because No Manufacturer Ever Received Approval to Market Generic Tamoxifen

The injury here (higher prices for tamoxifen) resulted from the existence of the '516 patent and not the Settlement Agreement, and because the purported injury flowed from the result of a lawful patent monopoly, no antitrust injury can exist. For example, in *NYNEX v. Discon, Inc.*, 525 U.S. 128 (1998), the Supreme Court held that no injury flowed from a regional Bell operating company's unilateral decision to refuse to deal with one company. *Id.* at 136-37. Similarly, no antitrust injury occurs when a patent holder sues for infringement unless the patent was fraudulently procured or the infringement action was a sham. *In re Independent Services Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000). Nor can a defendant in a patent

infringement suit claim antitrust injury based on the costs of defending against the infringement or related costs caused by losing the infringement suit. *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1558 (Fed. Cir. 1997), *partially overruled on other grounds by, Cybor Corp. v. FAS Tech, Inc.*, 138 F.3d 1444 (Fed. Cir. 1998) (en banc).

Plaintiffs contend that Defendants caused injury because the Settlement Agreement was structured to license tamoxifen to Barr only at supra-competitive prices. (Pl. Opp. Mem. at 35.) Plaintiffs thus argue that this case is similar to *Ciprofloxacin*, where the court found that the allegation that the patentee would have negotiated licenses with generic manufacturers at *competitive* prices sufficed to allege antitrust injury. 166 F. Supp. 2d 740, 749 (E.D.N.Y. 2001). Even liberally interpreting the Complaint to encompass such allegations (which it does not) and despite the language in *Ciprofloxacin*, Defendants are correct to the extent that Plaintiffs are alleging injury based on the possibility that Zeneca would license its patent at competitive prices. As the Federal Circuit has noted, "[t]here is no reported case in which a court ha[s] imposed antitrust liability for a unilateral refusal to sell or license a patent." *Independent Services Orgs.*, 203 F.3d at 1326 (internal quotations omitted). No antitrust injury can flow from the prices at which Zeneca licensed tamoxifen to Barr.

Plaintiffs' injuries thus must flow from the anti-competitive nature of the Settlement Agreement. As described above, this would entail proof of injury not from the decision by Zeneca to settle the patent litigation, but from the exclusion of other competitors in the market. However, as Defendants note, no generic manufacturer ever obtained FDA approval to bring the drug to market since all three manufacturers who filed with paragraph IV certifications failed to prove in court that the patents were invalid.

Antitrust injury, however, must be caused by something other than the regulatory action limiting entry to the market. For example, no antitrust injury was found where a potential competitor to a local electrical utility in Pittsburgh merged with the existing utility before receiving permission to compete from the state regulatory agency. *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 267-68 (3d Cir. 1998). Similarly, another court has found that no antitrust injury existed to support an antitrust counterclaim brought by a second ANDA filer since it would not be able to compete in the market until (1) the patent was declared invalid and (2) the 180-day exclusivity period expired for the first filer. *See Bristol-Meyers Squibb v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 23 (D. Mass. 2000).

In the present case, the lack of competition in the market was not caused by the deployment of Barr's exclusivity period, but rather by the inability of the generic companies to invalidate or design around the '516 Patent. Indeed, in *Bristol-Meyers*, *supra*, the possibility of antitrust injury was more proximate since the second ANDA filer would have been able to enter the market relatively soon after the first ANDA filer. Here, absent any allegations that Barr conspired with Zeneca somehow to hinder either Novopharm, Pharamchemie or Mylan from establishing the invalidity of the '516 patent, there is no basis for the claim that competition could have existed. In this respect, the present case is quite different from *Terazosin*, where Geneva had received approval to begin marketing a generic capsule of terazosin, or from Procardia XL case, where Biovail in fact received approval to market its generic version despite the allegedly anti-competitive efforts to delay its entry.

Plaintiffs do argue that Barr's FDA Petition delayed approval of Mylan's ANDA, and that therefore this action prevented Mylan from marketing its generic version of tamoxifen. (Pl. Opp. Mem. at 37.) Even assuming that the Complaint alleges that Mylan would have marketed its

generic tamoxifen before receiving a court order in its favor,[12] given the actual judgment against it in favor of Zeneca, Mylan never could have entered the market without infringing upon the '516 Patent. Plaintiffs, in other words, allege injury based on the lack of competition that could have only existed by illegally infringing on the '516 Patent. The lack of competition was not the result of any anti-competitive conduct by Zeneca or Barr, but rather the result of the existence of the '516 patent and the decision by the patent holder to enforce it. It is thus not antitrust injury, but rather the result of the legal monopoly that a patent holder possesses. *Cf. Eastman Kodak*, 114 F.3d at 1558 ("The cause of [claimant's] injuries was not that Eastman enforced the [acquired] patent, but that the patent was enforced at all. These injuries, therefore, did not occur 'by reason' of that which made the acquisition allegedly anticompetitive.").

B. Plaintiffs Cannot Allege Antitrust Injury Based on the Settlement Agreement Resuscitating the '516 Patent

Plaintiffs' other claim of injury is essentially that the settlement and *vacatur* deprived other generic manufacturers of the ability to make the legal argument that the *ICI v. Barr* judgment (if affirmed) would collaterally estop Zeneca from claiming the '516 patent was valid in future patent litigation with other ANDA filers. At the time of settlement, however, Barr had no vested right in the judgment still on appeal. *See Asselta v. 149 Madison Ave. Corp.*, 79 F. Supp. 413, 415 (S.D.N.Y. 1948) ("A complainant has not any vested right in the decree of the district court while it is subject to review."). If Barr had no such right, it is hard to imagine how other generic manufacturers had legitimate expectations that they could rely upon the judgment

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[12] The Complaint merely alleges that *Barr* (in its FDA Petition) claimed that Mylan "likely will begin marketing a generic version upon receiving FDA approval." (Compl. ¶ 66.) This is somewhat different from *Plaintiffs* claiming that Mylan would enter the market before actually obtaining a declaration that the '516 Patent was invalid (and thus risking monetary liability for infringing on the patent).

on appeal as well. Yet Plaintiffs now seek to base an injury upon the elimination of a judgment on which not even Barr could rely. Plaintiffs point to no case that establishes this result, namely, that forcing other generic manufacturers to litigate the validity of the '516 patent, is an injury to competition.

It must be noted that in light of the Federal Circuit's later decision in *Novopharm* affirming a district court's decision *upholding* the validity of the '516 patent, plaintiffs' supposition that the Federal Circuit would have affirmed Judge Broderick's decision declaring the '516 patent invalid is also unwarranted. Of course, the *Novopharm* decision could not prevent other generic manufacturers from challenging the patent. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1429 (Fed. Cir. 1988) (Federal Circuit's prior decision upholding patent's validity not binding on another challenge in the courts or the Patent and Trademark Office); *Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1091 (Fed. Cir. 1987) (a manufacturer charged with patent infringement will not be collaterally estopped from challenging the validity of the patent as part of its defense to the infringement claim even if the patent's validity was upheld in a prior infringement suit involving a different manufacturer). And when Pharmachemie and Mylan continued their challenges to the validity of the '516 patent even after the *Novopharm* decision, that decision had no impact on the merits of their claims. As noted previously, those challenges failed as well.

Absent any cognizable injury, the Sherman Act claim is dismissed.

III. The Claims for Restitution

Count II alleges that under state common law (*see* Pl. Opp. Mem. at 61) Zeneca has benefitted from unlawfully charging supra-competitive prices, that Barr has benefitted from unlawfully receiving payments from Zeneca and receiving funds from the sales of the licensed

tamoxifen to the Plaintiffs, and that therefore equity demands that Defendants disgorge these benefits. (Compl. ¶¶108-115.)

Under the current Draft Restatement, "[a] person who is unjustly enriched at the expense of another is liable in restitution to the other." Restatement (Third) of Restitution & Unjust Enrichment § 1 (Discussion Draft Mar. 31, 2000). Plaintiffs are correct that the state of the common law most likely recognizes unjust enrichment as a source of obligation with its own remedial structure. However, a restitution claim requires that Defendants have "unjustly," *id.*, or "wrongfully" received a benefit. *Geller v. County Line Auto Sales, Inc.*, 81 F.3d 18, 22 (2d Cir. 1996).

Plaintiffs' allegations of enrichment focus entirely upon the ability of Zeneca and Barr to charge monopolistic prices for tamoxifen after the Settlement Agreement. As held above, based on plaintiffs' allegations there was nothing impermissible about Zeneca charging monopolistic prices or licensing tamoxifen to Barr. Since whatever benefit received by Zeneca or Barr was not wrongfully secured, no restitution is available. *Id.* ("Because the defendants were not unjustly enriched, a restitution award is not available.") Count II of the Complaint thus is also dismissed.

IV. Plaintiffs' Other State Law Claims

A. Antitrust Claims

Plaintiffs bring state law claims under the antitrust laws of 17 states: Arizona, California, the District of Columbia, Florida, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, New Jersey, New York, North Carolina, North Dakota, South Dakota, West Virginia, and Wisconsin. Plaintiffs and Defendants agree that state antitrust law should be construed

similarly to federal antitrust law where possible.[13] (*See* Def. Consolidated Mem. at 36 and n.15 (collecting cases and official opinions); Pl. Opp. Mem. at 69 n. 39 (collecting more cases and noting statutory directives).) Accordingly, since Plaintiffs fail to state a claim under the Sherman Act, and since the state antitrust law claims are based on the same allegations, those claims are also dismissed.

B. Unfair Competition and Consumer Protection Laws

Plaintiffs also assert that the Defendants' actions violated consumer protection and unfair competition laws in 21 states: Arizona, California, Florida, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin.

These state unfair competition laws generally prohibit sellers from engaging in unfairly competitive practices (such as agreements to divide the market) or otherwise making false promises or misrepresentations to the consumer public. Plaintiffs' claims sound wholly in allegations of unfair competition based on the Settlement Agreement that track entirely the allegations underlying the antitrust claims.

However, in order to state a claim under state unfair competition laws related to the enforcement of a patent, "bad faith must be alleged and ultimately proven." *Zenith Electronics Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1355 (Fed. Cir. 1999). Otherwise, the claims are preempted by patent law. *Id.* For the reasons already noted, the Complaint fails to allege facts that indicate

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[13] The parties disagree on one point not relevant to the present discussion – whether the *Illinois Brick* rule (prohibiting indirect purchasers from asserting federal antitrust claims) also governs state antitrust law claims where the states in question have not definitively ruled on the issue. Since the allegations otherwise fail to state a claim, this disagreement is immaterial.

that Zeneca and Barr acted in bad faith in settling their patent litigation for purposes of federal law. The same result governs the state law claims.

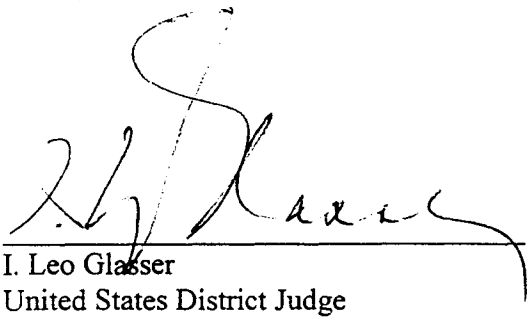
Accordingly, the state unfair competition law claims are also dismissed.

CONCLUSION

For the foregoing reasons, the motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) is granted.

SO ORDERED.

Dated: May 30, 2003
Brooklyn, New York



I. Leo Glasser
United States District Judge

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